UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
Case No. 1:17-cv-31

KRISTIANA TWEED BURRELL, individually, and as ADMINISTRATRIX OF THE ESTATE OF ARIEL GRACE BURRELL, deceased, Plaintiff, v. BAYER CORPORATION; BAYER HEALTHCARE LLC; BAYER ESSURE INC., f/k/a/ CONCEPTUS, INC.; BAYER HEALTHCARE PHARMACEUTICALS INC., CHRISTOPHER FORD WILLIAMS; DR. STACY D. TRAVIS; and BILTMORE OB-GYN, P.A., Defendants.	**JURY TRIAL DEMANDED**

NOTICE OF REMOVAL

Defendants Bayer Corporation, Bayer Essure Inc., Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc. (together, "Bayer"), and Mr. Christopher Ford Williams, by and through their undersigned counsel, hereby provide notice pursuant to 28 U.S.C. §§ 1331, 1441, and 1446 of the removal of the above-captioned case from the General Court of Justice of Buncombe County, North Carolina to the United States District Court for the Western District of North Carolina. The grounds for removal are as follows:

1. On or about December 16, 2016, Plaintiff filed a Complaint in North Carolina state court in this civil action styled *Kristiana Tweed Burrell v. Bayer Corp. et al.* The Complaint alleges that Plaintiff suffered various injuries, including the stillbirth of a child, as a

result of her experiences using Essure, an FDA-approved Class III medical device that serves as a form of permanent female birth control. *See* Ex. A (Complaint).

2. FDA approved Essure through the rigorous premarket approval ("PMA") process in 2002. Ex. B (Premarket Approval Order). Since then, FDA has granted numerous supplemental approvals, including as recently as December 2016, *see* Ex. C (FDA website noting PMA Supplements). It has repeatedly reviewed and approved Essure's design, construction, manufacturing, testing, training requirements, warnings, instructions for use, patient information, and all other labeling. *See generally Norman v. Bayer Corp.*, No. 3:16-cv-253, 2016 WL 4007547, at *1-2 (D. Conn. July 26, 2016) (recounting Essure regulatory history and dismissing all claims with prejudice as preempted by federal law).

3. After a public hearing in September 2015 and months of investigation, FDA reaffirmed that "FDA believes Essure remains an appropriate option for the majority of women seeking a permanent form of birth control." Ex. D (FDA News Release (Feb. 29, 2016)).

4. In addition to this Notice of Removal, Bayer will be filing a Motion to Dismiss. The Motion to Dismiss will demonstrate that all of Plaintiff's claims are preempted and inadequately pled.

5. As set forth more fully below, this Court has jurisdiction because there is federal-question jurisdiction. This case involves a medical device that was approved by FDA after receiving the highest level of scrutiny available in the federal regulatory system. Less than 1% of medical devices receive this rigorous federal approval. *See Walker v. Medtronic, Inc.*, 670 F.3d 569, 572-73 (4th Cir. 2012). In addition, FDA has continued to review Essure intently. This ongoing review has included public hearings addressing the same federal regulatory issues that form the premise of this lawsuit. *See* Ex. D (FDA News Release (Feb. 29, 2016)).

6. Plaintiff pleads violations of federal law on the face of her Complaint. Plaintiff's right to relief turns on resolution of the federal-law questions. The exercise of federal-question jurisdiction here will not disrupt the balance between state and federal jurisdiction, in light of the extraordinary federal involvement in the very issues that are at the heart of this case, and the small number of medical devices subject to such extraordinary federal oversight. *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312-14 (2005); *see also Jenkins v. Medtronic, Inc.*, 984 F. Supp. 2d 873, 878 (W.D. Tenn. 2013) (finding federal question jurisdiction because state-law product liability claims regarding PMA medical device required the court "to examine federal law, and, even more specifically, examine federal requirements imposed by the FDA through the premarket approval process"); *H.R. ex rel. Reuter v. Medtronic, Inc.*, 996 F. Supp. 2d 671, 677-78 (S.D. Ohio 2014) (similar).

I. THE PROCEDURAL REQUIREMENTS OF REMOVAL ARE MET.

7. Pursuant to 28 U.S.C. § 1446(a), true and correct copies of all process, pleadings, orders and other documents filed in the state court action are attached as Exhibit A.

8. Plaintiff's Complaint was served on Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc. on December 27, 2016. The Complaint was served on Bayer Essure Inc. on January 4, 2017. Christopher Ford Williams was served on December 31, 2016. Section 1446(b)(1) requires a notice of removal to be filed within 30 days of the service of a complaint upon the defendants. *See Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 354 (1999) (30-day time limit for removal runs from date of formal service of the initial complaint). Because 30 days from December 27, 2016, is January 26, 2017, this Notice is timely filed.

9. The United States District Court for the Western District of North Carolina is the district court for the district embracing the place where the state court action is now pending. It is therefore a proper forum for removal. *See* 28 U.S.C. §§ 113(c), 1441(a).

10. All Defendants consent to removal. *See* 28 U.S.C. § 1446(b)(2)(A). A copy of Dr. Stacy D. Travis and Biltmore Ob-Gyn, P.A.'s consent to removal is attached hereto as Exhibit E.

11. A copy of this Notice of Removal is being served on Plaintiff, and a copy is being filed with the state court. *See id*. § 1446(d).

12. If any questions arise about this removal, Bayer respectfully requests the opportunity to present briefing and oral argument in support of removal.

II. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1331 AND 1441.

13. This Court has federal question jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1441.

14. Federal question jurisdiction exists where a plaintiff pleads federal violations on the face of the complaint and "the vindication of a right under state law necessarily turn[s] on some construction of federal law." *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808 (1986) (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 9 (1983)). This principle "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable*, 545 U.S. at 312. "[T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum

may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.* at 314.

15. Thus, federal question jurisdiction exists where, on the face of the complaint, a "federal issue [is] (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Pressl v. Appalachian Power Co.*, 842 F.3d 299, 303 (4th Cir. 2016).

16. These factors are met here, in the context of a PMA medical device that FDA heavily regulates, as other well-reasoned cases have held. *See Jenkins*, 984 F. Supp. 2d at 878 (finding federal question jurisdiction over state-law product liability claims regarding PMA medical device because claims required court to decide questions of federal law); *Reuter*, 996 F. Supp. 2d at 677-78 (similar); *cf. Bowdrie v. Sun Pharm. Indus., Ltd.*, 909 F. Supp. 2d 179, 184-85 (E.D.N.Y. 2012) (finding federal question jurisdiction in product liability drug case where "boundaries of Plaintiffs' claims . . . are established by the FDCA").

17. Here, Plaintiff's claims against Bayer turn on whether Bayer violated federal regulatory requirements. *See* § II.A, *infra*. Moreover, FDA's recent investigation into and response to the very issues that are the subject of this case renders the federal interest particularly substantial. This substantial interest warrants the exercise of federal jurisdiction to resolve the overwhelmingly federal issues of law at issue in this case. *See* Compl. ¶¶ 132-40, 178.

A. Plaintiff's Right To Relief Depends On The Resolution Of Substantial And Disputed Federal Questions.

18. Plaintiff expressly predicates her state-law claims on numerous alleged violations of federal requirements. For example, Plaintiff alleges that Bayer:

a. "violated federal and state law by, *inter alia*: receiving and failing to warn of or report many of the approximately 30,000 complaints about Essure® to the FDA or the public; failing to warn of or report Essure®'s failure to

meet its performance specifications or perform as intended under the CPMA and FDA requirements; and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about Essure®," Compl. ¶ 172;

b. "marketed, advertised, and promoted Essure® while failing to warn or otherwise ensure the safety of its users in violation of … the Essure® CPMA and FDA regulations," *id.* ¶ 173;

c. "negligently failed to comply with [federal] requirements and failed to take necessary actions—such as filing PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitted MDRs—to advise users of Essure® of the defects and risks described above," *id.* ¶ 175; and

d. "[v]iolat[ed] the following federal regulations [that] also constitute violations of the Bayer Defendants' parallel state law duties and give rise to negligence *per se*: 21 C.F.R. § 803.10; 21 C.F.R. § 803.50; 21 C.F.R. § 803.52; 21 C.F.R. § 803.53; 21 C.F.R. § 803.56; 21 C.F.R. § 806; 21 C.F.R. § 814.1; 21 C.F.R. § 814.3; 21 C.F.R. § 814.9; 21 C.F.R. § 814.20; 21 C.F.R. § 814.37; 21 C.F.R. § 814.39; 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. § 820.5; 21 C.F.R. § 820.20; 21 C.F.R. § 820.22; 21 C.F.R. § 820.25; 21 C.F.R. § 820.30; 21 C.F.R. § 820.70; and 21 C.F.R. § 820.160," *id.* ¶ 198.

19. These allegations of federal violations are not tangential: Plaintiff's right to relief "necessarily turn[s] on" their resolution. *Pressl*, 842 F.3d at 303. As part of the Medical Device Amendments, Congress adopted a "general prohibition on non-Federal regulation" of medical devices. H.R. Rep. No. 94-853, at 45 (1976). The MDA expressly preempts "any requirement" imposed by state law relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a). As the Supreme Court held in *Riegel v. Medtronic, Inc.*, premarket approval of a Class III medical device establishes the federal "requirements" applicable to that device. 552 U.S. 312, 321-23 (2008). It also held that state-law tort claims impose state-law requirements. *Id.* at 323-25. Thus, to the extent state-law causes of action claim that Bayer breached duties "different from, or in addition to" federal requirements, they are expressly

preempted. *Id.* at 330. In other words, as the Eighth Circuit has explained, a "plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a))." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)) (emphasis omitted); *see also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1342 (10th Cir. 2015) (dismissal of claims required because plaintiff failed to "identif[y] any legally viable federal requirement that might parallel and thus permit her claims"). Thus, Plaintiff cannot succeed on her state-law claims unless she shows that Bayer violated a federal requirement. *See Walker*, 670 F.3d at 577.

20. Here, Plaintiff "set the landscape" when she pleaded violations of federal law on the face of her own Complaint. *Jenkins*, 984 F. Supp. 2d at 880. It is no answer to suggest that the federal-law questions arise only in the context of a preemption defense. In rejecting a similar attempt to defeat federal question jurisdiction, another court explained that "Plaintiffs have set the landscape and scope of the issues that would be addressed in this case," and the fact that "Defendants have properly asserted an applicable preemption defense to Plaintiffs' claims" does not deprive the court of jurisdiction. *Jenkins*, 984 F. Supp. 2d at 880; *but see Johnson v. Bayer Corp.*, No. 4:16-cv-729, 2016 WL 3015187, at *3 (E.D. Mo. May 26, 2016).

21. FDA's involvement in this matter has been extraordinary: FDA not only has conducted the usual stringent PMA review, but FDA also has specifically investigated *the very matters* that are the subject of Plaintiff's claims and has determined that Essure remains "an appropriate option for the majority of women seeking a permanent form of birth control." FDA News Release (Feb. 29, 2016) (Ex. D). That federal involvement here is crucial to the analysis of whether federal question jurisdiction exists. *See Gilmore v. Weatherford*, 694 F.3d 1160, 1174 (10th Cir. 2012) ("The involvement of the federal government in [the] dispute is a key

factor."). Plaintiff is seeking to second-guess this federal law determination by a federal agency. Indeed, "[t]here can be little doubt that this dispute is far more material to the federal government than" a typical product liability claim. *Id.* at 1175. Adjudicating the inherently federal claims at issue here in a federal forum properly recognizes and protects the significant federal interest in this case.

B. Federal Jurisdiction Will Not Disrupt the Federal-State Balance.

22. For similar reasons, the exercise of federal jurisdiction will not disrupt the careful balance between federal and state law that Congress has created. Federal jurisdiction here would "portend only a microscopic effect on the federal-state division of labor"—namely, those cases in which FDA has taken specific steps to address the alleged issues that are the subject of Plaintiff's Complaint. *Grable*, 545 U.S. at 315. At the same time, federal question jurisdiction guarantees that important and necessary federal issues of law are decided in federal court. *See Reuter*, 996 F. Supp. 2d at 680.

23. Accordingly, the exercise of federal question jurisdiction is necessary and appropriate here.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Defendants Bayer Corporation, Bayer Essure Inc., Bayer HealthCare LLC, Bayer HealthCare Pharmaceuticals Inc., and Ford Williams hereby demand a jury trial on all triable issues in this action.

CONCLUSION

WHEREFORE, Notice is given that this action is removed from the General Court of Justice in Buncombe County, North Carolina to the United States District Court for the Western District of North Carolina.

This the 26th day of January, 2017.

ELLIS & WINTERS LLP

s/ Stephen D. Feldman
Stephen D. Feldman
N.C. Bar. No. 34940
Emily E. Erixson
N.C. Bar. No. 47136
4131 Parklake Avenue, Suite 400
Raleigh, NC 27612
Tel: 919.865.7000
Fax: 919.865.7010
stephen.feldman@elliswinters.com
emily.erixson@elliswinters.com

Rebecca K. Wood *(pro hac vice to be filed)*
Jonathan F. Cohn *(pro hac vice to be filed)*
SIDLEY AUSTIN LLP
1501 K Street, NW
Washington, DC 20005
Tel: 202.736.8000
Fax: 202.736.8711
rwood@sidley.com
jfcohn@sidley.com

Attorneys for Defendants Bayer Corporation, Bayer HealthCare LLC, Bayer Essure Inc., Bayer HealthCare Pharmaceuticals Inc., and Christopher Ford Williams

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on January 26, 2017, the foregoing Corporate Disclosure Statement was served on counsel of record by depositing a copy thereof in the United States mail, postage prepaid, first class, addressed as follows.

John C. Cloninger
CLONINGER, BARBOUR,
SEARSON, JONES & CASH, PLLC
21 Battery Park Avenue, Suite 201
Asheville, NC 28801

Rand P. Nolen
George Fleming
Jessica Kasischke
FLEMING | NOLEN | JEZ, LLP
2800 Post Oak Blvd., Suite 4000
Houston, TX 77056

Attorneys for Plaintiff Kristiana Tweed Burrell, individual, and as Administratrix of the Estate of Ariel Grace Burrell, deceased

John D. Kocher
SHUMAKER, LOOP & KENDRICK, LLP
101 South Tryon Street, Suite 2200
Charlotte, NC 28280

Attorney for Defendants Dr. Stacy D. Travis And Biltmore OB-GYN, P.A.

s/ Stephen D. Feldman
Stephen D. Feldman

Attorney for Bayer Corporation, Bayer HealthCare LLC, Bayer Essure Inc., Bayer HealthCare Pharmaceuticals Inc., and Christopher Ford Williams